Aortic Valve Neocuspidization Procedure Provides Better Postoperative Outcomes When Compared to Rapid Deployement Aortic Valves

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ABSTRACT

Background: The aim of this study was to compare the early results of rapid deployment aortic valves (RD-AVR) and aortic valve neocuspidization (AVNeo) techniques.

Methods: Between December 2019 to May 2022, 104 patients were operated on with aortic stenosis by RD-AVR (N = 52) and AVNeo (N = 52) techniques. Patients with isolated aortic valve stenosis and aortic stenosis concomittant with planned other cardiac surgeries were included.

Results: The mean age of patients in the RD-AVR and AVNeo groups were 67.4 ± 7.8 vs. 62.9 ± 8.7 , respectively. Aortic cross-clamp time in the RD-AVR group was 56.7 ± 23.3 minutes, while it was 104.1 ± 27.9 minutes in the AVNeo group (P < 0.001). Cardiopulmonary bypass time in the RD-AVR group and in the AVNeo group was 89.8 ± 27.6 minutes and 141.8 ± 36.7 minutes, respectively (P < 0.001). Permanent pacemaker become necessary in four patients in the RD-AVR group secondary to type 2 AV block. Paravalvular leak was observed in six patients, who underwent RD-AVR, while grade 2 central aortic regurgitation was observed in one patient in the AVNeo group. Hospital mortality was 8% in the RD-AVR group and 6% in the AVNeo group (P = 0.696).

Conclusions: AVNeo procedure is a feasible technique in all age groups of patients with successful hemodynamic results in the early postoperative period and with the advantage of not requiring anticoagulants. It also can be applied with other cardiac surgical interventions.

]INTRODUCTION

Approximately two-thirds of all heart valve surgeries are aortic valve replacements (AVR). Surgical AVR remains the gold standard for aortic valve disease treatment, with good

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Correspondence: Prof. Kubilay Karabacak, Health Sciences University, Gülhane School of Medicine, Department of Cardiovascular Surgery, Ankara, Turkey, 06010, Telephone +903123045205 (e-mail: kubilaykarabacak@yahoo.com) postoperative and long-term outcomes in relatively lowrisk patients [Ashikhmina 2011]. Although the long-term outcomes of mechanical valves are known, the requirement for lifelong anticoagulation, as well as higher morbidity and death rates due to bleeding and thromboembolic events, make mechanical valves less appealing to many surgeons. With technological advances in the design of bioprosthetic valves and the identification of new surgical techniques, there has been a marked increase in the use of rapidly implantable or "sutureless" aortic valves (RD-AVR) in elderly and more fragile patients with high comorbidities in the last decade. Despite technical breakthroughs in both mechanical and biological prosthetic valve design and fabrication, their hemodynamic performance cannot be matched to that of natural aortic valves. It has been suggested that RD-AVR reduces the cross-clamp (X-clamp) and cardiopulmonary bypass (CPB) times and thus the surgical risk [Al-Sarraf 2011]. Aortic valve repair operations, on the other hand, are performed seldom and exclusively for a restricted set of patients with aortic valve disease by a few expert facilities. As a result, aortic valve neocuspidization (AVNeo) has arisen as a new treatment option for a variety of aortic valve diseases. A case series of 88 patients was published by Ozaki in 2011, and in this series, aortic valve reconstruction with autologous pericardium treated with glutaraldehyde was recommended in patients with aortic valve disease [Ozaki 2011]. One of the main advantages of this method is that it does not require long-term anticoagulation, and natural aortic root enlargement is achieved with the maximum effective orifice area in systole compared with aortic valve replacement [Karabacak 2022]. With the publication of successful medium-term results, the AVNeo procedure has found application in increasing frequency. Currently, there is no literature comparing the two techniques, although data are available for both procedures. In the literature, it is seen that RD-AVR is mostly implanted with the MIS approach. Therefore, we aimed to compare the perioperative and postoperative results of RD-AVR performed by conventional full sternotomy with the patient group who underwent AVNeo.

MATERIALS AND METHODS

Study design: In this retrospective cohort analysis, 104 patients were operated on with aortic stenosis between

December 2019 to May 2022. Fifty-two of them were operated with RD-AVR, while the remaining 52 patients were operated with AVNeo technique. Data retrospectively were collected. Transthoracic echocardiography (TTE) routinely was performed by the same physician in all patients preoperatively for the standardization. Aortic annulus diameter routinely was measured from CT angiography in both groups. Preoperative demographic variables, echocardiographic variables, and associated disorders were recorded and analyzed. Local ethical committee was approved the study. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Inclusion criteria: The inclusion criteria were as follows: patients who were operated with isolated aortic valve stenosis and aortic stenosis concomitant with coronary bypass surgery and/or other heart valve surgery. Patients who were operated with minimally invasive approaches and those with isolated aortic valve insufficiency were excluded.

Surgical approach: All surgical procedures were performed with the same surgical team in both groups. Standardized median sternotomy and aortic and bicaval cannulation routinely were performed. Cardiopulmonary bypass was initiated with mild hypothermia, and cardiac arrest was maintained with antegrade blood cardioplegia. Aortotomy was performed 1.5 cm above the ostium of the right coronary artery in all patients. Aortic valve resection and decalcification of annulus were similar in both groups. In the RD-AVR group, Edwards Intuity sutureless valve (Edwards Lifesciences, LLC, Irvine, CA) was used. This is a balloon expandable, stented, tri-leaflet bovine pericardial bioprosthetic valve that was implanted after standardized sizing protocol as instructed. In the AVNeo group, the surgical procedure was performed as described in previous papers Ozaki 2018; Ozaki 2014. Briefly, gluterhaldehide-preserved autologous pericardium was sewn in to the aortic annulus as a neo-leaflet, after the sizing procedure and resection of native leaflets. Aortotomy was closed as usual after implantation procedure, and the operation was terminated with standardized techniques in both groups. Intraoperative transesophageal echocardiography (TEE) routinely was performed to all patients for examining the new aortic valve.

Postoperative management: All patients were followed by a 24-hour event recorder telemetry (Infinity® M300, Draeger Medical Systems Inc, USA) in the intensive care unit and also during the clinical course. Pacemaker implantation was planned in patients with type 2 AV block, after a sevenday waiting interval. TTE was performed on all patients on discharge by the same physician. Three-month oral anticoagulation and lifelong acetyl salicylic acid treatment were given to all patients in the RD-AVR group, while only acetyl salicylic acid treatment was given to patients in the AVNeo group for three months. All patients were followed with electrocardiography (ECG) and TTE at six months and annually thereafter.

Statistics: Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS) program version 26.0 for Windows (IBM Corporation, Armonk, NY). Visual (histograms, probability plots) and analytical methods (Kolmogorov-Smirnov, Shapiro-Wilk's test) were used to

determine whether the variables were normally distributed. Normally distributed continuous variables are expressed as mean± SD, non-normally distributed continuous variables as median (first and third quartile), and categorical variables as numbers and percentages. Students' t-test was used for comparing the normally distributed variables, the Mann Whitney U test for comparing the non-normally distributed variables, and Chi-square test or Fisher's exact test was used to evaluate the differences in proportions. A P-value less than 0.05 was considered statistically significant.

RESULTS

Study population: Gender distribution and the age of the patients were similar between the RD-AVR group and AVNeo group (46% vs. 44%, P = 0.844, and 67.4± 7.8 and 62.9 ± 8.7, P = 0.324, respectively). There also were no significant differences on EuroSCORE II score between the groups (7.2% ± 3.07 % vs. 5.1 ± 3.9 %, P = 0.280). Aortic stenoregurgitation was seen in eight (15%) patients in the RD-AVR group and in nine (17%) patients in the AVNeo group (P = 0.732). There were no statistically significant differences between the groups, in terms of other preoperative patient characteristics. Demographic variables and preoperative characteristics of patients are summarized in Table 1.

Operative variables: Mean CPB time (89 ± 27.6 min vs. 141 ± 36.7 min; P < 0.001) and aortic cross-clamp time (56.7 ± 23.3 min vs. 104.1 ± 27.9 min, P < 0.001) were significantly shorter in the RD-AVR group. Additional cardiac surgery was performed in 28 (54%) patients in the AVNeo group and in 14 (27%) in the RD-AVR group (P = 0.005). In patients undergoing isolated aortic valve surgery, mean CPB and ACC time were shorter in the RD-AVR group than in the AVNeo group. (76.6 ± 10.6 min, 113.8 ± 21.8 min; P < 0.001 and 45.1 ± 8.1 min, 79.2 ± 8.9 min; P < 0.001, respectively). Remaing operative data are summarized in Table 2.

Preoperative CT angiorgaphy revealed the mean aortic annulus diameters were 22.7 \pm 2.22 mm and 23.1 \pm 2.02 mm in the RD-AVR goup and in the AVNeo group, respectively (*P* = 0.927). RD-AVR 19 mm, 21 mm, 23 mm, 25 mm, and 27 mm were implanted in seven (13%), 22 (42%), 12 (23%), five (10%), and six (10%) patients, respectively. No patient in either group underwent root enlargement procedure.

Postoperative outcomes are summarized in Table 3. The hospital mortality was similar between the two groups. In the AVNeo group, three patients died, due to non-cardiac causes as follows: one patient from a cerebrovascular event, one patient from sepsis, and one patient from mesenteric ischemia. In the RD-AVR group, two patients died, due to a cerebrovascular event, and two patients died, due to multiorgan failure. One patient in the AVNeo group with moderate aortic insufficiency was reoperated on in the second postoperative month.

The frequency of new-onset atrial fibrillation was similar between the groups (P = 0.446). However, the frequency of new pacemaker implantation secondary to type 2 AV block was 8% in the RD-AVR group, while no pacemaker was

required in the AVNeo Group. ICU stay time and hospital stay time were similiar between the groups.

Postoperative echocardiogarphic variables: Echocardiography was performed by the same physician to the patients at discharge, sixth months, and at one year. Follow-up echocardiograpic data are shown in Table 4. At discharge and at six months, echocardiographic evaluation was performed in 48 RD-AVR patients and 49 AVNeo patients. Medical records of the postoperative first year could not be reached in two patients, who underwent RD-AVR and one patient who underwent AVNeo. The mean and peak gradient of the aortic neovalves were found significantly lower in the AVNeo group than in the RD-AVR group at discharge and all follow-up times. The mean LVEF was similar between the groups at all follow-up time points.

Discharge echocardiography revealed paravalvular leaks in six patients (four mild, two moderate) in the RD-AVR group, while there were no paravalvular leaks in the AVNeo group. These six patients were followed up with serial echocardiography and in two of the patients, a Percutaneous Amplatzer Occluder Device (St. Jude Medical, St. Paul, MN) successfully was implanted at the third month. The remaining four patients still are asymptomatic, and they are followed by annual echocardiography.

Aortic regurgitation was seen in eight patients in the AVNeo group at discharge; seven of them were grade I and one was grade II. The patient with grade II aortic insufficiency was reoperated on in the second postoperative month. At one year post-operation, a total of eight patients had grade I aortic regurgitation.

DISCUSSION

Despite advanges in aortic valve technology, such as transcathater aortic valve implantation procedures, aortic valve replacement is still a preferred choice, especially in elderly and high-risk patients with aortic stenosis [Shrestha 2013]. However, the ideal prosthesis has not yet been developed. Prosthetic valves are associated with various anatomical and physiologic problems due to stent ring. Stent ring may disrupt the physiological movement ability of aortic annulus. It also may cause the patient-prosthesis mismatch secondary to decreasing the aortic valve area [Mooney 2017].

Variable	RD-AVR group ($N = 52$)	AVNeo group (N = 52)	P-value	
Age (years), mean ± SD	67.4 ± 7.8	62.9 ± 8.7	0.324	
Female, n (%)	24 (46%)	23 (44%)	0.844	
Body mass index (kg/m2), mean \pm SD	28.5 ± 5.7	$\textbf{28.9} \pm \textbf{3.5}$	0.680	
Smoking, n (%)	13 (25%)	11 (21%)	1.000	
Chronic obstructive pulmonary disease, n (%)	10 (19%)	5 (10%)	0.175	
Diabetes mellitus, n (%)	13 (25%)	6 (11%)	0.492	
Arterial hypertension, n (%)	34 (65%)	27 (52%)	0.163	
Renal insufficiency, n (%)	10 (19%)	8 (15%)	0.604	
Peripheral vascular disease, n (%)	5 (6%)	1 (2%)	0.196	
EuroSCORE II (%), mean ± SD	7.2 ± 3.07	5.1 ± 3.9	0.280	
NYHA functional classification, n (%)				
I	7 (13%)	8 (16%)		
II	13 (25%)	20 (38%)	0.429	
III	29 (56%)	22 (42%)	0.456	
IV	3 (6%)	2 (4%)		
Coronary artery disease, n (%)	25 (48%)	17 (33%)	0.110	
LV ejection fraction (%), mean \pm SD	54.9 ± 11.8	55.5 ± 9.1	0.831	
Aortic valve area (mm2), mean \pm SD	0.86 ± 0.21	0.89± 0.22	0.426	
Aortic anulus diameter, (mm), mean \pm SD	22.7 ± 2.22	23.1 ± 2.02	0.927	
Peak aortic gradient (mmHg), mean \pm SD	80.1 ± 25.8	80.8 ± 15.3	0.850	
Mean aortic gradient (mmHg), mean \pm SD	49.9 ± 14.3	50.2± 10.9	0.426	

Table 1. Baseline patient characteristics

RD-AVR, rapid deployment aortic valve replacement; AVNeo, aortic valve neocuspidizadition; LV, left ventricle; NYHA, New York Heart Association; SD, standard deviation

Table 2. Patient operative data

Variable	RD-AVR group ($N = 52$)	AVNeo group (N = 52)	<i>P</i> -value
Aortic annulus diameter (mm), mean \pm SD	22.7 ± 2.22	23.1 ± 2.02	0.927
Isolated aortic valve surgery, n (%)	38 (73%)	24 (46%)	0.005
Other surgical procedure, n (%)			
Coronary artery bypass surgery	10 (19%)	15 (29%)	0.251
Mitral valve surgery	3 (6%)	8 (15%)	0.111
Ascending aortic surgery	2 (4%)	8 (15%)	0.046
Pulmonary valve replacement	-	1 (2%)	0.320
Tricuspid ring annuloplasty	1 (2%)	-	0.320
Cardiopulmonary bypass time (min), mean \pm SD	89.8 ± 27.6	141.8 ± 36.7	<0.001
Isolated	76.6 ± 10.6	113.8 ± 21.8	<0.001
Combined	128.2 ± 24.7	164.1 ± 30.3	<0.001
Aortic cross clamp time (min), mean \pm SD	56.7 ± 23.3	104.1 ± 27.9	<0.001
Isolated	45.1 ± 8.1	79.2 ± 8.9	<0.001
Combined	88.3 ± 21.8	123.8 ± 21.1	<0.001

RD-AVR, rapid deployment aortic valve replacement; AVNeo, aortic valve neocuspidizadition; SD, standard deviation

Table 3. Postoperative outcomes

Variable	RD-AVR group ($N = 52$)	AVNeo group (N = 52)	P-value		
Acute renal insufficiency, n (%)	4 (8%)	3 (6%)	0.696		
Cerebrovascular events, n (%)	2 (4%)	1 (2%)	0.558		
New cardiac arrhythmia					
Atrial fibrillation, n (%)	11 (21%)	8 (15%)	0.446		
Type 2 AV-block, n (%)	5 (10%)	1 (2%)	0.205		
Permanent pacemaker implantation, n (%)	4 (8%)	0	0.041		
Sternal wound infections, n (%)	2 (4%)	3 (6%)	0.647		
Reoperation for bleeding, n (%)	2 (4%)	3 (6%)	0.549		
Hospital mortality, n (%)	4 (8%)	3 (6%)	0.696		
Length of ICU stay, days (median, IQR)	2 (1-7)	2 (1-7)	0.746		
Length of hospital stay, days (median, IQR)	8 (5-13)	8 (5-16)	0.347		

AV-block, atrio-ventricular block; ICU, intensive care unit

The rapid deployment aortic valves (RD-AV) and/or sutureless aortic valves (SAV) offer many advantages. They require relatively short surgical time and have better hemodynamical performances. However, high paravalvular leak rates, relatively higher residual gradient rates, higher pacemaker implantation rates, and relatively higher costs are the major disadvantages of these valves, which makes their use controversial [Andreas 2016; Ferrari 2017].

AVNeo procedure was defined in 2007 by Ozaki et al. and still can be used in all aortic valve pathologies [Ozaki

2011]. The most important advantages of AVNeo procedure include that it allows anatomical and physiological movement of the aortic annulus and creation of an effective orifice area close to the natural aortic valve. The autologous pericardium treated with gluteraldehide provides similar mechanical and hemodynamic performance with native aortic valve [Meuris 2016]. On the other hand, the most important disadvantage of the AVNeo procedure is the long learning curve period and, accordingly, partial longer ACC time [Karabacak 2021].

	Preoperative		Discharge		Sixth month			First year			
	RD-AVR group (N = 52)	AVNeo group (N = 52)	RD-AVR group (N = 48)	AVNeo group (N = 49)	P-value	RD-AVR group (N = 48)	AVNeo group (N = 48)	P-value	RD-AVR group (N = 46)	AVNeo group (N = 47)	P-value
Peak aortic gradient, mmHg, mean ± SD	83.1±21.8	79.3±14.2	21.4±3.4	20.1±3.1	0.042	19.0±3.0	17.7±2.7	0.025	17.7±3.0	15.9±2.6	0.003
Mean aortic gradient, mmHg, mean \pm SD	51.2±12.6	48.2±8.72	11.1±2.1	9.8±2.1	0.005	9.6±2.1	8.7±1.8	0.047	8.9±1.8	7.7±2.1	0.004
LVEF (%), mean \pm SD	54.9±11.8	55.4±9.1	54.8±8.2	55.7±7.8	0.557	56.1±6.4	57.1±5.8	0.422	57.2±5.1	58.6±4.6	0.165
Paravalvular leak, n (%)	-	-	6 (12.5)	-	0.012	4 (8.3)	-	0.041	4 (8.7)	-	0.036
Aortic regurgitation, grade, n (%)											
l (Trace)	-	-	-	7 (14.3)	-	-	7(14.6)	-	-	8 (17)	-
II (Mild)	-	-	-	1 (2)	-	-	0	-	-	0	-
III (Moderate)	-	-	-	0	-	-	0	-	-	0	-
IV (Severe)	-	-	-	0	-	-	0	-	-	0	-

Table 4. Postoperative echocardiographic data

LVEF, left ventricular ejection fraction

Aortic cross-clamping and cardiopulmonary bypass times: In the current study, mean ACC time and CPB times were found as 45.1 ± 8.1 and 76.6 ± 10.6 minutes in patients who underwent the isolated RD-AVR procedure and $88.3 \pm$ 21.8 and 128.2 ± 24.7 minutes in patients who had concomitant cardiac surgery to RD-AVR procedure. Wahlers et al. reported their ACC and CPB time in patients with isolated RD-AVR as 43 ± 32 vs. 71 ± 41 minutes [Wahlers 2016]. Similarly, Ferrari et al. reported their mean ACC time and CPB time as 36.7 ± 10.5 minutes and 52 ± 10.7 minutes for isolated RD-AVR and 72.8 ± 26.4 minutes and 94 ± 27.5 minutes for concomitant surgery [Ferrari 2017]. Both studies have acceptable ACC and CPB time for RD-AVR procedure.

On the other hand, AVNeo procedure takes longer ACC time and CPB time compared with RD-AVR techniques. Learning curve is the main controversial issue regarding AVNeo procedure. Ozaki et al. defined the learning curve as at least 20 patients [Ozaki 2014]. As it was expected, our study mean ACC time and CBP time were found significantly longer in the AVNeo group than the RD-AVR group. Consistent with our results, Ozaki et al. reported that the mean ACC time was 110.1 \pm 26.8, and mean CPB time was 149.4 \pm 29.9 minutes in isolated aortic valve procedures [Ozaki 2014]. In a meta-analysis designed by Sohn et al., patients with RD-AVR surgery and conventional bioprosthetic surgery were compared [Sohn 2018]. As expected, the ACC time and CPB time were found significantly shorter in the RD-AVR group. However, the risk of postoperative complications, such as acute renal failure, atrial fibrillation, bleeding reoperation, prolonged ventilation, stroke, and both early mortality and all-cause mortality during follow up, was similar between the two groups, which suggests that the time extension caused by the operative technique could not translate into worsened postoperative outcome. Consistent

with Sohn et al. [Sohn 2018], in our study, although ACC time and CPB time were significantly longer in the AVNeo group, postoperative complications and early mortality rates were similar between the groups.

Hemodynamic results: In recent years, many randomized studies have been conducted showing the superiority of the hemodynamic performance of the RD-AVR valve over conventional aortic valve replacement. Borger et al. reported that the echocardiographic transvalvular gradient was significantly lower at 3-month follow up in the RD-AVR group compared with conventional AVR (10.3 and 8.5 mmHg, respectively, P = 0.044) [Borger 2015]. Many studies show that RD-AVR has hemodynamic advantages over stented aortic valve. Andreas et al. and Wahlers et al. compared RD-AVR with conventional AVR and reported similar differences [Andreas 2016; Wahlers 2018]. In our study, mean aortic gradient was found in the RD-AVR group as 11.1 ± 2.1 , 9.6 ± 2.1 and 8.9 ± 1.8 mmHg at discharge, 6- and 12-month controls, which is consistent with current literature.

In the AVNeo procedure, there is no prosthetic stent ring, and the glutaraldehyde fixed autologous pericardium is directly sutured into the native aortic annulus. As a result, the aortic gradient is much lower than all other prosthetic valves. This technique also has much better hemodynamic results as it does not change the anatomical structure of the annulus and the commissures, thus allows normal physiological annular movements and dynamics without reducing the valve's functional area. In a study, Yamamato et al. reported the aortic annular dimensions after AVNeo procedure were found similar to the dimensions of normal aortic valves [Yamamato 2017]. In fact, despite advances in bioprosthesis technologies and all efforts to create a thinner stent rings, it has not yet been technically possible to preserve the natural and physiological dynamics of the aortic root [Formica 2018]. In our study, although a statistically significant decrease was detected in aortic gradients in both groups, the decrease in the AVNeo group was much more striking, which highlights the importance of the native aortic annular physiology and absence of a stent ring.

Pacemaker implantation: In literature, known risk factors to pacemaker implantation in patients who underwent aortic valve replacement include age, female gender, annular calcification, bicuspid aortic valve, hypertension, CPB time, and comorbid cardiac pathologies [Erdogan 2006]. The pathophysiology of this dominance mainly depends on aortic stenosis and annular and valvular changes of the aortic valve. In aortic stenosis, the leaflets are fused, valvular attachment approaches the ventriculoarterial junction, and leaflet tissue moves close to the conduction system, which results in rhythm disturbances [Lenders 2014].

In a large German registry, the rate of pacemaker implantation was found to be 8.8% in the RD-AVR [Ensminger 2018]. In another recent study by D'Onofrio et al., the incidence of pacemaker implantation was reported as 6.3% in patients with the RD-AVR valve system [D'Onofrio 2022]. RD-AVR valves are designed to sit below the level of the aortic ring; therefore, RD-AVR may increase the possibility of conduction disturbances more than conventional aortic valve replacement. The RD-AVR valve system may cause conduction abnormalities secondary to its balloon expandable anchoring system. In our study group, four (8%) patients needed permanent pacemaker implantation secondary to new-onset type 2 AV block in the RD-AVR group. Our results are compatible with the papers that determined postoperative pacemaker necessity at 5%-11% [Wahlers 2016; Barnhart 2017]. On the other hand, there was no pacemaker necessity in the AVNeo group, which also is compatible with current literature [Reuthebuch 2018].

Paravalvular leak and aortic regurgitation: Paravalvular leak (PVL) is one of the most important complications that can be seen in the early and late postoperative period after implantation of the RD-AVR system. Inadequate sizing and positioning are well-known reasons associated with PVL [Englberger 2014; Ferrari 2015]. Patients with inadequate decalcification, especially in the presence of asymmetrical aortic annulus, provide the other potential risk factor for PVL. The effect of PVL on late mortality rates is controversial. Although, some studies declared that mild or 1-degree PVL has no effect on mortality rates, in another study, the authors showed mild PVL had negative effects on survival [Vola 2015].

In literature, the rates of moderate-to-severe PVL were reported as between 1.4% and 3% at discharge and between 3% and 7% at 1-year follow up [Kocher 2013; Schlömicher 2015]. In our study, moderate PVL was only seen in two patients in the RD-AVR group at the early postoperative period, consistent with literature. Percutaneous Amplatzer occluder Device (St. Jude Medical, St. Paul, MN) successfully were implanted to these two patients. Also, mild PVL was seen in four patients after RD-AVR. Annual echocardiography was planned for these patients because their hemodynamic and biochemical parameters were stable. In the AVNeo group, no PVL was seen. With AVNeo technique, there is no annular ring that may implanted to the annulus. The neoleaflets are directly sewn onto the aortic annular wall, after complete resection of native leaflets, calcifications and fibrotic tissue that may cause incomplete implantation and PVL. However, there may be an incomplete coaptation and central aortic regurgitation secondary to inadequate sizing or inapproiate suture technique in the AVNeo procedure. It is very important that the coaptation line is formed in accordance with the technique and is in the same plane after the suture of the three leaflets prepared from the autologous pericardium in the AVNeo technique. The success of the AVNeo technique mainly depends on aortic annulus sizing.

On the other hand, while aortic regurgitation was not seen in RD-AVR, in the AVNeo group trace aortic regurgitation was seen in seven (14.3%) patients and mild aortic regurgitation in only one (2%) patient at discharge. The patient with second-degree eccentric aortic regurgitation was reoperated at the second postoperative month, due to the progressive worsening of symptoms. Similarly, in another study from Ozaki et al., which reported the mid-term results of 850 patients treated with AVNeo, the recurrence rate of moderate and severe AR was found as 7.3% [Ozaki 2018].

Limitations: This was a retrospective study, so it has potential design limitations. It also is a single-center study with a small study population; therefore, it is difficult to generalize results. Finally, a relatively short follow-up period may be another limitation.

CONCLUSION

AVNeo procedure is a feasible and effective technique in all age groups of patients with aortic valve pathologies. Important benefits to this technique include better hemodynamic outcomes, no necessity to use anticoagulants, lower paravalvular leak rates, and lower pacemaker implantation rates. It also has similar mortality and morbidity rates with other aortic surgical interventions. In conclusion, the AVNeo method is a viable treatment with positive hemodynamic outcomes in the early postoperative phase. It also can be performed concomittant with other cardiac surgical procedures.

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